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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,516	08/20/2003	Steven K. MacLeod	01288/2/US	5971
26648 7590 07/31/2007 PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			EXAMINER DEAK, LESLIE R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 07/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,516

Applicant(s)

MACLEOD, STEVEN K.

Examiner

Leslie R. Deak

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 11 August 2006. These drawings are accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al in view of US 5,549,561 to Hjertman.

In the specification and figures, Crankshaw discloses the invention substantially as claimed by applicant. With regard to claims 1-3,

In particular, Crankshaw discloses the structure of a vial 11 with two chambers 13, 14 a stopper 17 intermediate the chambers, and an upper stopper 23. Crankshaw discloses that movement of the upper stopper is an actuating means that pushes the intermediate stopper out of its seal with the constricted portion 16 of the vial, allowing the contents of the two chambers to mix within the combined volume of the two chambers. Crankshaw further discloses the cap 44 over the top of the stopper, a thin wall of the stopper for needle piercing, and the connections, sleeves, and locks of the claimed vial (see, generally, columns 2-4).

Crankshaw fails to disclose that the upper chamber is filled with an aqueous suspension and the lower chamber is filled with a gaseous medium. Crankshaw does teach, however, that the purpose of the two-compartment vial is to provide a stable storage solution wherein two substances, which may include a medication, may be stored completely independently from one another. Such independent storage is used when the combination of the substances in the first and second vials reduces the stability and shelf life of the combined solution or medicine. Hjertman discloses a medicament vial with a first and second chamber 6, 7, separated by barrier 8, and a third chamber 15 filled with a gaseous medium, separated by barrier 13. During operation, the compartments 6 and 7 are combined, creating a single chamber with an aqueous suspension therein, separated from gaseous chamber 15 by barrier 13 (see FIG 2, column 5). This arrangement allows for the storage of incompatible components in a single vial while providing sufficient headspace in chamber 15 to mix the medicament prior to patient administration (see column 6, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the vial disclosed by Crankshaw with the aqueous suspension and empty chamber disclosed by Hjertman in order to provide sufficient space for agitation prior to patient administration, as taught by Hjertman.

Hjertman does not specifically disclose that the barrier 13 is a gas impermeable barrier. However, Hjertman discloses the placement of two discrete substances, one including a gaseous medium, in the chambers surrounding the barrier 13. Such a disclosure reasonably suggests to one of ordinary skill in the art that the barrier 13 is

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made from a gas impermeable material to prevent the gaseous medium in chamber 15 from migrating through the barrier 13 to chamber 6/7. Accordingly, the instantly claimed invention is not patentably distinct from the prior art.

4. Claims 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al in view of US 5,549,561 to Hjertman, further in view of US 6,481,435 to Hochrainer et al.

Crankshaw and Hjertman disclose the device substantially as claimed by applicant (see rejection above) with the exception of the contents and relative formulations of the medicament within the vessel.

Hochrainer discloses that steroids such as, for example, clobetasol and meprednisone, among others, are often packaged in two-chambered dispensing vials in suspensions for administration to a patient in various concentrations (see column 4, lines 5-12, 38-50, columns 5-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the vial disclosed by Crankshaw with a desired medicament for a particular medical treatment, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07, citing *In re Leshin*, 125 USPQ 416. Applicant has not provided any evidence of unexpected results with regard to the storage or use of the particularly claimed medicament compositions. Accordingly, Hochrainer clearly shows the use of medication, as noted above, a person of ordinary skill in the art would recognize that medication having the

particular material claimed would be used in the medicament storage and dispensing vial suggested by Crankshaw and Hjertman, absent any showing of such new and unexpected results over the prior art.

Response to Arguments

5. Applicant's arguments, see Appeal Brief filed 7 May 2007, with respect to the rejection(s) of the pending claim(s) under Crankshaw and Hochrainer have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Crankshaw, Hjertman, and Hochrainer, as presented above. The rejection presented *supra* is a non-final rejection, and the finality of the office action mailed 16 March 2006 has been withdrawn.

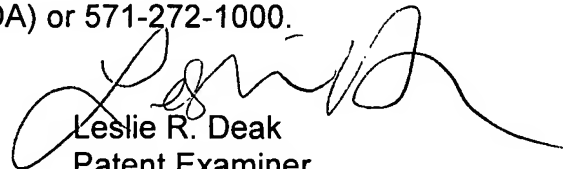
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
25 July 2007